EXHIBIT 3

IN THE MEIGS COUNTY COURT OF COMMON PLEAS
POMEROY, OHIO

Meigs County, Ohio
100 East Second Street
Pomeroy, Ohio 45769

Plaintiff,

v.

Cardinal Health, Inc.
R/A CT Corporation System
4400 Easton Commons Way, Suite 125
Columbus, OH 43219

and

Kroger Limited Partnership II
Corporation Service Company
50 West Broad Street, Suite 1330
Columbus, OH 43215

and

Miami-Luken, Inc.
William Powers
265 Pioneer Blvd.
Springboro, OH 45066

and

Purdue Pharma L.P.
R/A The Prentice-Hall Corporation
System, Inc.
251 Little Falls Drive
Wilmington, DE 19808

and

Purdue Pharma Inc.
R/A Corporation Service Company
80 State Street
Albany, NY 12207

and

FILED
COMMON PLEAS COURT
NOV 08 2018
SAMANTHA MUGRAGE
CLERK OF COURTS
MEIGS COUNTY, OHIO

Case No. 18-CV-083

Judge

JURY DEMAND ENDORSED HEREON

The Purdue Frederick Company, Inc.
R/A The Prentice-Hall Corporation System, Inc.
251 Little Falls Drive
Wilmington, DE 19808

and

Teva Pharmaceuticals USA, Inc.
Corporate Creations Network Inc.
119 E. Court Street
Cincinnati, OH 45202

and

Cephalon, Inc.
R/A Corporate Creations Network, Inc.
3411 Silverside Road Tatnall Building, Suite 104
Wilimington, DE 19810

and

Johnson & Johnson
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933

and

Janssen Pharmaceuticals, Inc.
CT Corporation System
4400 East Commons Way, Suite 125
Columbus, OH 43219

and

Ortho-McNeil-Janssen Pharmaceuticals, Inc.
N/K/A Janssen Pharmaceuticals, Inc.
1125 Bear Harbor Road,
Titusville, New Jersey, 08560

and

Janssen Pharmaceutica, Inc.
N/K/A Janssen Pharmaceuticals, Inc.

1125 Bear Harbor Road, Titusville
New Jersey, 08560.

and

Endo Health Solutions Inc.
R/A The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilimington, DE 19801

and

Endo Pharmaceuticals, Inc.
CT Corporation System
4400 Easton Commons Way, Suite 125
Columbus, OH 43219

and

Allergan PLC F/K/A Actavis PLC
5 Giralda Farms
Madison, NJ 07940

and

Actavis Pharma, Inc.
F/K/A Watson Pharmaceuticals, Inc.
Corporate Creations Network Inc.
119 E. Court Street
Cincinnati, OH 45202

and

Watson Laboratories, Inc.
Corporate Creations Network, Inc.
119 E. Court Street
Cincinnati, Ohio 45202

and

Actavis LLC
R/A Corporate Creations Network, Inc.
3411 Silverside Road Tatnall Building,
Suite 104
Wilimington, DE 19810

and

Mylan Bertek Pharmaceuticals Inc.
Corporation Service Company
50 West Broad Street, Suite 1330
Columbus, OH 43215

and

Allergan Finance LLC
R/A The Corporation Trust Company of Nevada
701 S. Carson Street, Suite 200
Carson City, NV 89701

and

Rite Aid of Ohio, Inc.
CT Corporation
1300 E. 9th Street
Cleveland, OH 44114

and

Walgreen Co.
The Prentice-Hall Corp. System, Inc.
50 West Broad Street, Suite 1330
Columbus, OH 43215

and

Mckesson Corporation
Corporation Service Company
50 West Broad Street, Suite 1330
Columbus, OH 43215

and

Amerisourcebergen Drug Corporation
CT Corporation System
4400 Easton Commons Way, Suite 125
Columbus, OH 43219

and

CVS Indiana L.L.C.
One CVS Drive
Legal Department
Woonsocket, RI 02895

and

Wal-Mart Stores East, LP
CT Corporation System
4400 Easton Commons Way, Suite 125
Columbus, OH 43219

and

Brandon Worley
4462 Rock Ridge Ln.
Akron, OH 44333

and

Donald Leathers
3031 Hillside Ave.
Springfield, OH 45503

Defendants.

COMPLAINT

Plaintiff, Meigs County ("Plaintiff" or "Meigs County"), by and through the undersigned attorneys, upon personal knowledge as to their own acts and beliefs, and upon information and belief as to all matters based upon the investigation of counsel, for their Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc.; Janssen Pharmaceutica, Inc. n/k/a/ Janssen Pharmaceuticals; Endo Health Solutions, Inc.; Endo Pharmaceuticals,

Inc.; Allergan PLC f/k/a Actavis plc; Allergan Finance, LLC f/k/a Actavis Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Allergan Finance; Mylan Bertek Pharmaceuticals Inc.; (collectively, "Manufacturers" or "Defendants"); Cardinal Health, Inc.; Kroger Limited Partnership II; Miami-Luken, Inc.; Rite Aid of Ohio, Inc.; Walgreen Co.; McKesson Corporation; AmerisourceBergen Drug Corporation; CVS Indiana, L.L.C.; Wal-Mart Stores East LP (collectively, "Distributor Defendants" or "Defendants"); and Brandon Worley; and Donald Leathers ("Sales Representative Defendants" and "Defendants") alleges as follows:

INTRODUCTION

1. Plaintiff spends money each year to provide or pay for the health care, pharmaceutical care, and other necessary services and programs on behalf of indigents and otherwise eligible residents, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

2. Plaintiff not only provide a wide range of other services on behalf of their residents, including services for families and children, public assistance, and law enforcement, but also depend on the health and productivity of its workforce to generate tax revenue.

3. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. These drugs are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and, therefore, are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.

4. Opioids provide effective treatment for short-term post-surgical and

trauma-related pain, and for palliative end-of-life care. Opioids are approved by the FDA for use in the management of moderate to severe pain and their use is typically appropriate for a few days or more. For example, doctors traditionally used opioids to treat acute pain for severe bodily trauma (*e.g.*, gunshot wounds and post-surgical pain). Patients experiencing extreme levels of pain from cancer have also received opioids to make the end of their life as pain free as possible. Defendants, however, have manufactured, promoted, and marketed opioids for the long-term management of chronic pain (*e.g.*, low back pain, knee pain, and neck pain) by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

5. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.[1] Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

6. Defendants knew that opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer ("chronic pain").

7. Defendants knew that, with prolonged use, the effectiveness of opioids wanes over time, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.[2]

8. Defendants knew that controlled studies of the safety and efficacy of opioids

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[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").
[2] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized.

9. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

10. Despite the foregoing knowledge, to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

11. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the 1990s, became more aggressive in or about 2006, and continues to the present.

12. Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients.

13. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, patients, governmental units, and others by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

14. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S.

nearly quadrupled.[3] In 2010, 254 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month. Also in that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).[4] While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[5] By 2014, nearly two million Americans either abused or were dependent on opioids.[6]

15. Defendants' campaign has been extremely profitable. In 2012 alone, opioids generated $8 billion in revenue for drug companies.[7] Of that amount, $3.1 billion went to Purdue for its OxyContin sales.[8]

16. Defendants' marketing campaign has been extremely harmful to Americans, including the citizens of and visitors to Meigs County, Ohio. Nationwide, overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses--seventy-eight deaths every day from an opioid overdose.[9]

17. In 2012, an estimated 2.1 million people in the United States suffered from

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[3] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed September 19, 2017) (internal footnotes omitted).
[4] M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).
[5] L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).
[6] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed September 19, 2017).
[7] B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).
[8] K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).
[9] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

substance use disorders related to prescription opioid pain relievers.[10] Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[11]

18. Opioid addiction and overdoses have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[12]

19. In 2016, approximately 64,000 people died from drug overdoses in the United States, more than the peak yearly death tolls from car crashes, HIV deaths, or gun deaths.[13] Sixty-six percent of the drug overdose deaths in 2016 involved opioids, with the total deaths involving opioids taking more lives than breast cancer.[14] The total overdose deaths in 2016 were 10,000 more than in 2015. The graph below shows the trend relating to overdose deaths since 2000:[15]

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[10] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

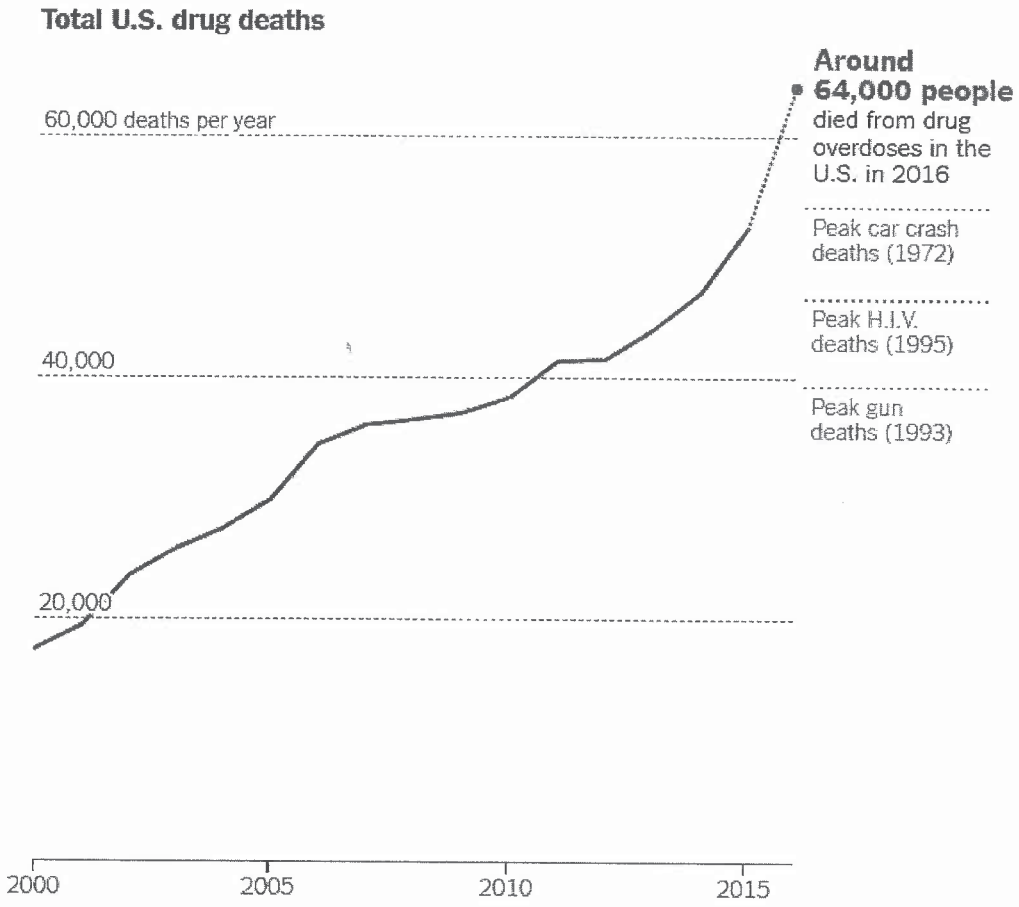
[11] J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) Addiction 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011).

[12] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed September 19, 2017).

[13] Katz, Josh, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html (published September 2, 2017, accessed October 27, 2017).

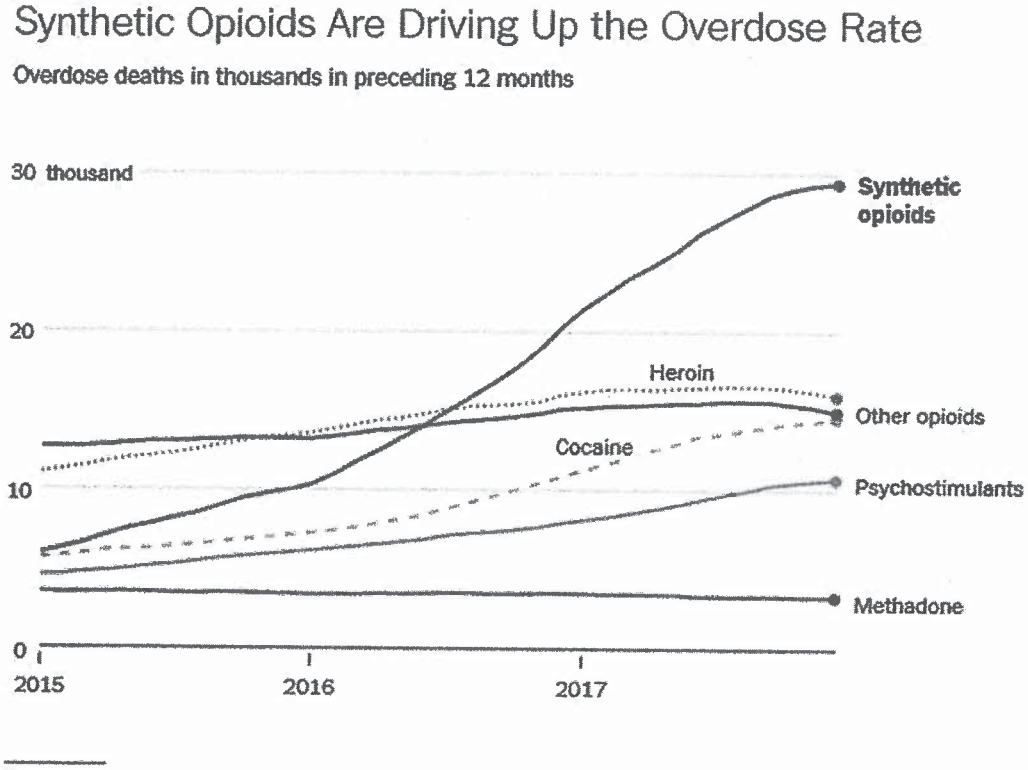
[14] Kounang, Nadia, *Opioids now kill more people than breast cancer*, http://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html (accessed December 29, 2017).

[15] Katz, Josh, *The First County of Fentanyl Deaths in 2016: Up 540% in Three Years*, *Supra*.



20. In 2017, 72,000 Americans died from drug overdoses, a rise in approximately 10% from 2016, according to new preliminary estimates from the Centers for Disease and Control. The number of deaths is higher than the peak yearly death totals from H.I.V., car crashes or gun deaths.[16] Strong synthetic opioids, particularly fentanyl, are driving up the overdose rate. The graph below shows the spike in overdose deaths from 2015 to 2017 due to synthetic opioids:[17]

[16] Margot Sanger-Katz. *Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017*. The New York Times: The Upshot. (August 15, 2018).
[17] Id.



21. Despite the record profits being generated from their efforts, Defendants' marketing campaign has failed to achieve any material health care benefits. Since 1999, there has been no overall change in the amount of pain that Americans report.[18]

22. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different

[18] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

purposes, and *aggressive marketing by pharmaceutical companies*."[19] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

23. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion[20] and the commission of criminal acts to obtain opioids throughout the United States, including in Ohio and Meigs County. Consequently, public health and safety throughout the United States, including Meigs County, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

24. Ohio has been especially ravaged by the opioid crisis.

25. Ohio has an opioid prescription rate of 100.1 per 100 persons, which ranks twelfth in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 41.3 per 100 persons which ranks twentieth nationally (U.S. median rate: 37.6).[21]

26. As reported by the Ohio Department of Health, Ohio has been among the states hardest hit by the opioid epidemic for years. From 2000 to 2015, Ohio's death rate due to unintentional drug poisonings increased 642 percent, driven largely by opioid-

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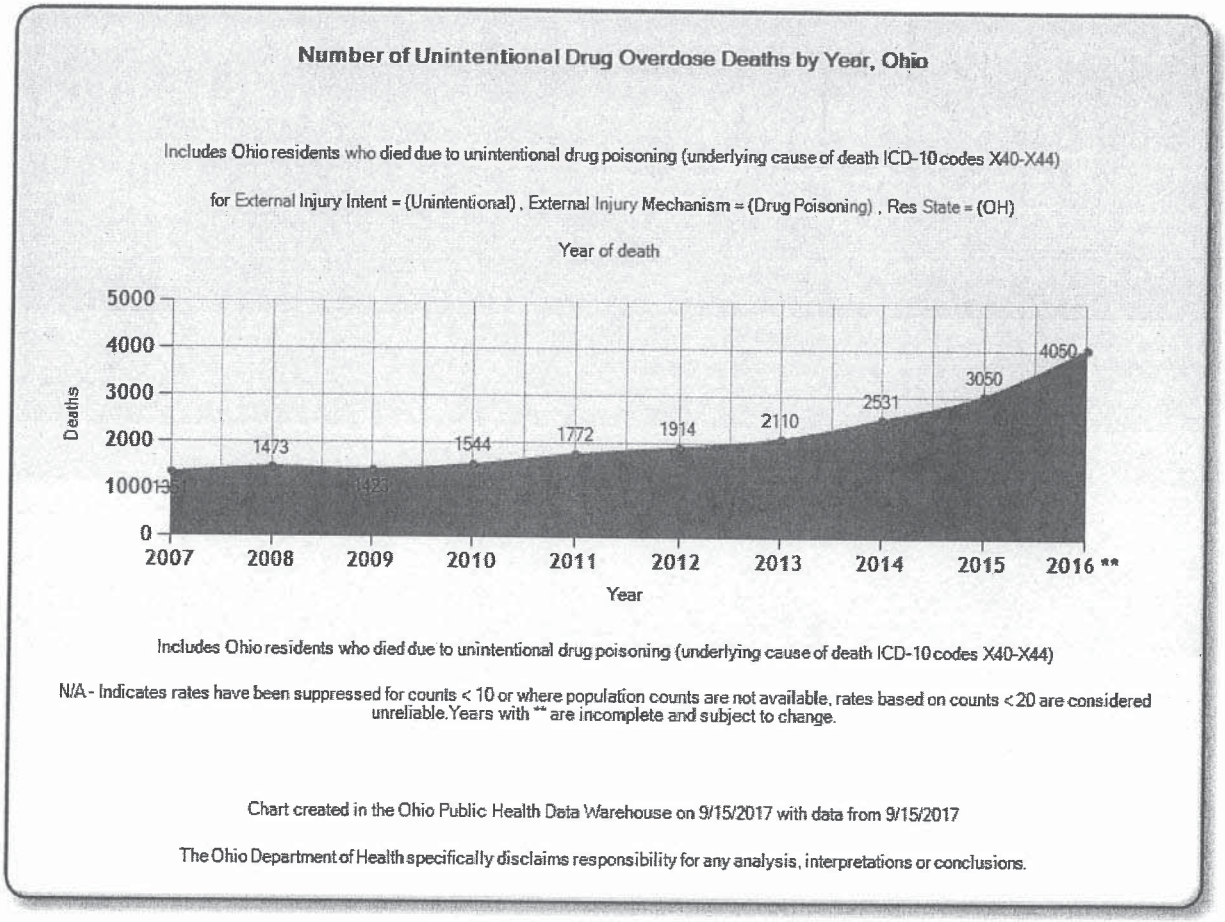
[19] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed September 19, 2017) (emphasis added).

[20] According to the CDC, when prescription medicines are obtained or used illegally, it is called "drug diversion."

[21] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743, https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf, (Published October 21, 2015, accessed October 25, 2017).

related overdoses.[22] In 2015, there were 3,050 Ohio overdose deaths, up 20.5 percent from 2,531 Ohio overdose deaths in 2014, with 85% of these overdoses involving opioids.[23] The problem is only getting worse: between 2015 and 2016, overdose deaths in Ohio rose by nearly 33 percent.[24]

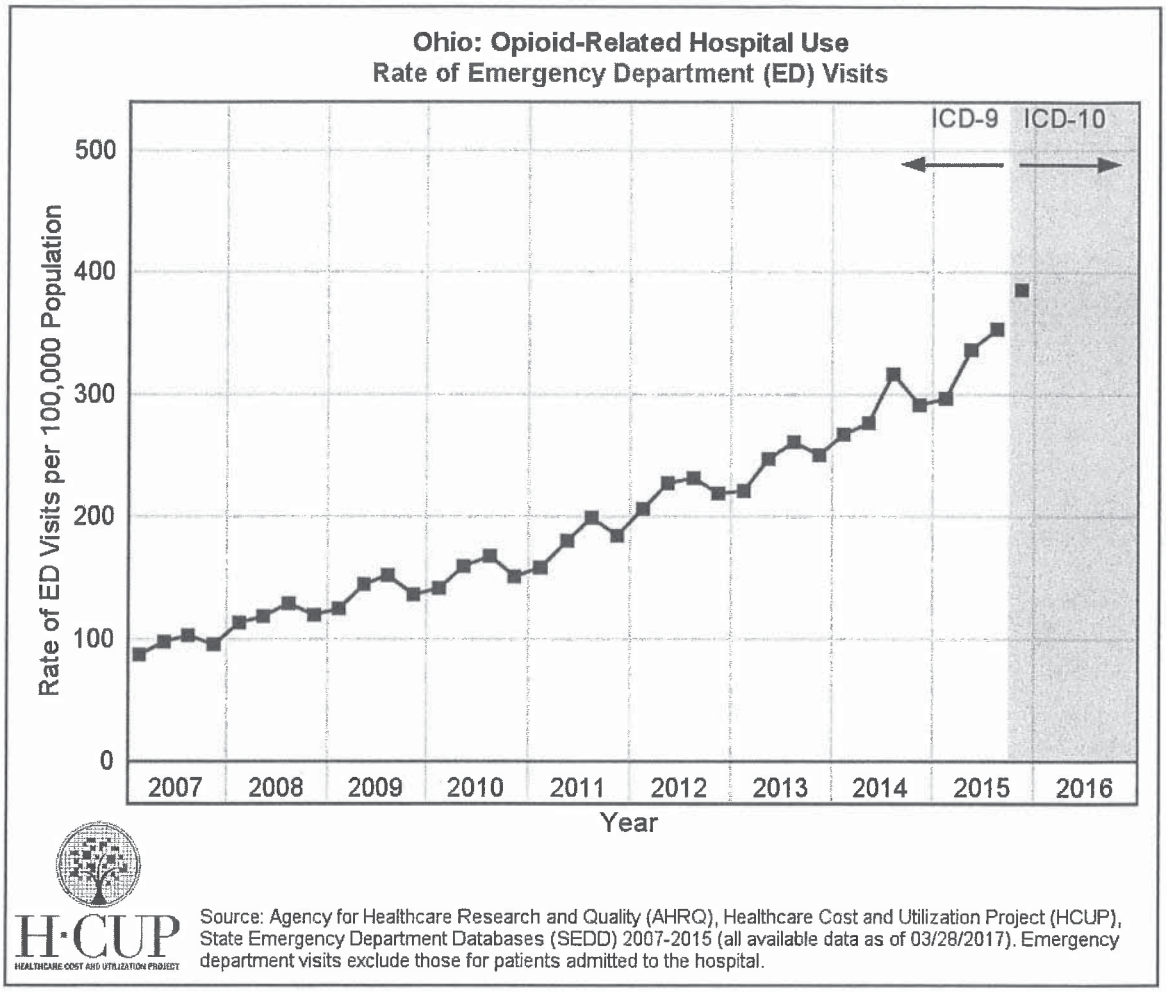


27. Unintentional fatal drug overdoses cost Ohioans $2.0 billion in 2012 in medical and work loss costs; while non-fatal, hospital-admitted drug poisonings cost an additional $39.1 million. The total cost equaled an average of $5.4 million *each day* in

[22] Ohio Department of Health, Prevalence and Trends in Unintentional Drug Overdose, https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx, (accessed October 25, 2017).
[23] *See* Governor's Cabinet Opiate Action Team website at http://fightingopiateabuse.ohio.gov/, (accessed October 25, 2017).
[24] Ohio Department of Health, *2016 Ohio Drug Overdose Data: General Findings*, https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en, (accessed October 25, 2017).

medical and work loss costs in Ohio.[25]

28. The rate of opioid related Emergency Department visits increased 106% in Ohio between 2009 and 2014.[26]



29. The Opioid epidemic is largely responsible for an 11 percent increase in children in state custody in Ohio in the past six years.[27] Seventy percent of infants placed

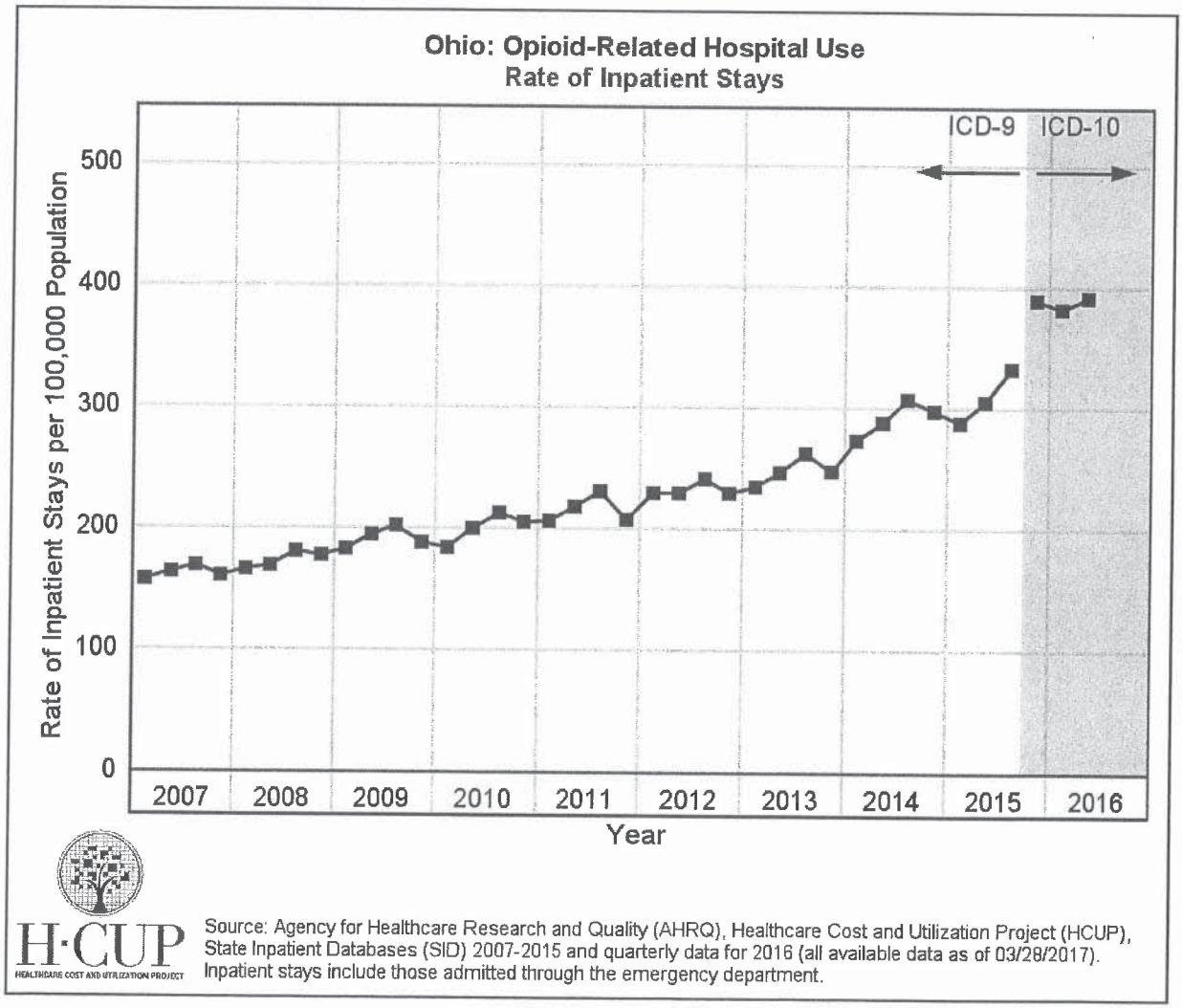
[25] Ohio Department of Health, *Cost to Ohio*, https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx, (accessed October 25, 2017).

[26] Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, *Statistical Brief #219, Opioid Related Inpatient Stays and Emergency Department Visits by State, 2009-2014*, https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf, (published December 15, 2016, revised January 26, 2017, accessed October 25, 2017).

[27] Public Children Services Association of Ohio, *Ohio's Opiate Epidemic and Child Protection (2016)*, http://www.pcsao.org/programs/opiate-epidemic, (accessed October 25, 2017).

in Ohio's foster care system are children of parents with opioid addictions.[28] Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes their care more expensive.[29]

30. Data maintained by the Agency for Healthcare Research and Quality for 2007 through 2016 document a sharp increase in opioid-related inpatient hospital stays in Ohio. The annual rate of such stays per 100,000 citizens has continued to increase:



[28] Ohio Child Welfare Opiate Engagement Project, http://www.pcsao.org/perch/resources/downloads/cw-opiate-white-paper-final-9-18-14.pdf, (published September 2014, accessed October 25, 2017).

[29] Trista Thurston, Newark Advocate, *Drug Addiction Drives Spike in Ohio Foster Care*, Newark Advocate, 2017), http://www.newarkadvocate.com/story/news/crime/high-in-ohio/2017/03/23/drug-addiction-drives-spike-ohio-foster-care/99545804/, (published March 23, 2017, accessed October 25, 2017).

31. Meigs County has not been an exception to the suffering caused by the opioid epidemic. According to one report from the Ohio Department of Health, the number of unintentional drug overdose deaths of Ohio residents and average crude and age-adjusted annual death rates per 100,000 population in Nobel County increased from 14 in 2003 to 2009, up to 21 in 2010 to 2015, showing an obvious increase in the death toll caused by Defendants' deceptive marketing practices.[30]

32. The devastating effects which include financial burden to the County healthcare system is clear. Tragically, between 2011 and 2015, 35.5 of every 1,000 babies were born with Neonatal Abstinence Syndrome in Meigs County, a condition where babies are born addicted to drugs.[31] The average hospital cost for a newborn with NAS is $66,700, compared to $3,500 for the typical newborn.[32]

33. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend a significant amount of money each year in their efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred and continue to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

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[30] Ohio Department of Health, *2015 Ohio Drug Overdose Data: General Findings*, https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2015-Overdose-Data/2015-Ohio-Drug-Overdose-Data-Report-FINAL.pdf, (last accessed November 5, 2018).

[31] Ohio Department of Health, *Number of Neonatal Abstinence Syndrome (NAS) Hospitalizations and the Average NAS Rate by County of Residence, Ohio 2011-2015*, https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/NAS-Rate.pdf?la=en, (last accessed November 5, 2018).

[32] National Institute on Drug Abuse, *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome, (last accessed November 5, 2018).

34. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*,: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment to infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered, directly by the Plaintiff. In sum, Plaintiff seeks to retrieve the costs needed to spend on efforts to clean up the disastrous epidemic caused by Defendants, which has infected nearly every aspect of civic life, and the cost required to repair the damage moving forward.

35. Plaintiff also seeks the means to abate the Defendants' wrongful and/or unlawful conduct creating this public health crisis.

JURISDICTION AND VENUE

36. This Court has jurisdiction over this action pursuant to Ohio Const. Article IV, § 4(B); Ohio Rev. Code Ann. § 1907.01; Ohio Rev. Code Ann. § 2305; Ohio Rev. Code Ann. § 2307.382(A)(1); Ohio Rev. Code Ann. § 2307.382(A)(3); Ohio Rev. Code Ann. § 2307.382(A)(4); Ohio Rev. Code Ann. § 2307.382(A)(6); and Ohio Rev. Code Ann. § 2307.382(A)(7).

37. Venue is proper in Meigs County pursuant to Ohio Civ. R. 3(b)(3).

38. This Court has personal jurisdiction over Defendants because they are incorporated in Ohio and/or have their principal place of business in Ohio, and /or conduct business in Ohio; purposefully direct or directed their actions toward Ohio; consented to be sued in Ohio by registering an agent for service of process; consensually submitted to the jurisdiction of Ohio when obtaining a manufacturer or distributor license; have headquartered in Ohio; have taken actions within Plaintiff's jurisdictional boundaries that have foreseeably caused injury to Plaintiff; and have the requisite minimum contacts with Ohio necessary to constitutionally permit the Court to exercise jurisdiction for adequate Due Process to Defendants.

39. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

PARTIES

40. Plaintiff, Meigs County, has a population of 23,080 as of the 2010 census.[33]

41. Plaintiff has duty to provide a wide range of services to their residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

42. Plaintiff brings this action on their own behalf. By incurring the costs and expenses and in making the payments it has made on behalf of its employees, residents, and visitors, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

43. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of the State of Delaware with its principal place of business at One

[33] https://www.census.gov/quickfacts/fact/table/meigscountyohio/PST045217.

Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

44. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

45. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

46. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Meigs County, including OxyContin (Oxycodone hydrochloride extended release), MS Contin (Morphine sulfate extended release), Dilaudid (Hydromorphone hydrochloride), Dilaudid-HP (Hydromorphone hydrochloride), Butrans (Byrenorpine), Hysingla ER (Hyrdrocodone bitrate), and Targiniq ER (Oxycdone hydrocholoride and Naloxone hydrochloride), all of which except Butrans are Schedule II.[34]

47. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

48. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware

[34] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. Of the Purdue drugs listed above, Butrans is the only Schedule III drug.

corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation with its United States Headquarters located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

49. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters at 1090 Horsham Road, North Wales, Pennsylvania 19454. In 2011, Teva Ltd. acquired Cephalon, Inc.

50. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally and in Meigs County, including Actiq (Fentanyl citrate) and Fentora (Fentanyl citrate tablet), both Schedule II drugs.

51. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Meigs County.

52. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its headquarters located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933.

53. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560 and is a wholly owned subsidiary of J&J.

54. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

55. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now

known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560.

56. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560.

57. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

58. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Meigs County, including Duragesic (Fentanyl), Nucynta (Tapentadol), and Nucynta ER (Tapentadol extended release), all of which are Schedule 2 drugs.[35]

59. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

60. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

61. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its headquarters at 1400 Atwater Drive,

[35] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

Malvern, Pennsylvania.

62. EHS and EPI (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Meigs County, including Opana ER (Oxymorphone hydrochloride extended release), Opana (Oxymorphone hydrochloride), Percodan (Oxymorphone hydrochloride and aspirin), and Percocet (Oxymorphone hydrochloride and acetaminophen).

63. Opioids make up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

64. Allergan PLC is a public limited liability company incorporated in Ireland with its principal place of business at Clonshaugh Business & Technology Park, Coolock, Dublin 17. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in March 2015.

65. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013. Actavis, Inc.'s headquarters are located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

66. Watson Laboratories, Inc. is a Nevada corporation with its headquarters at 132 Business Center Drive, Corona, California and is a wholly owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

67. Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and was formerly known as Watson Pharma, Inc.

68. Actavis LLC is a Delaware limited liability company with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

69. Each of the defendants in ¶¶ 66–70 are owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts; profits from the sale of Allergan/Actavis products; and ultimately benefits from them (Allergan PLC, Actavis PLC, Actavis, Inc., Allergan Finance LLC; Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.").

70. Actavis manufactures, promotes, distributes, and sells the branded opioids Kadian (morphine sulfate extended release) and Norco nationally and within Meigs County. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

71. Defendant Mylan Bertek Pharmaceuticals Inc. ("Mylan") is incorporated in West Virginia with its principle place of business located at 781 Chestnut Ridge Rd, Morgantown, West Virginia 26505. Mylan is registered to do business in Ohio. Mylan manufactures generic versions of three of the top four most sold opioids in the United States: Oxycodone, hydrocodone, and Methadone.[36] It additionally manufactures

[36]Stempniak, Marty, For of the Most Used Opioids, https://www.hhnmag.com/articles/7004-the-four-most-abused-opioids, (posted

Fentanyl. Mylan manufactures, promotes, distributes, and sells opioids nationally and within Ohio and Meigs County.

72. Defendant Rite Aid of Ohio, Inc. ("Rite Aid") was incorporated in Ohio in 1971 and has various locations throughout Ohio, including within Meigs County and acts as a subsidiary of Rite Aid Corporation.

73. Defendant Rite Aid distributes opioids to consumers within Ohio and Meigs County.

74. Defendant Walgreen Co. ("Walgreen") was incorporated in Illinois in 1909 and has various locations throughout Ohio, including within Meigs County. Both Walgreen and Rite Aid are collectively referenced in the remainder of the complaint as "Rite Aid."

75. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters at One Post Street, San Francisco, California, 94104.

76. McKesson promotes, distributes, and sells opioids manufactured by Manufacturers across the country and, upon information and belief, within Ohio and Meigs County to pharmacies and institutional providers. It had a net income over $1.5 Billion in 2015.

77. Defendant Cardinal Health Inc. ("Cardinal") is an Ohio Corporation with its headquarters at 7000 Cardinal Place, Dublin, Ohio, 43017.

78. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including, on information and belief,

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March 2, 2016, accessed April 11, 2018).

Ohio and Meigs County.

79. Upon information and belief, defendant Cardinal is one of the largest distributors of opioid pain medications in the Country, including the State of Ohio.

80. Defendant CVS Indiana, L.L.C. ("CVS") is an Indiana corporation with its principal place of business at Woonsocket, Rhode Island. Defendant CVS distributes opioids to consumers within Ohio and Meigs County.

81. Defendant Kroger Limited Partnership II ("Kroger") is an Ohio Limited Partnership with its principal place of business in Columbus, Ohio. Kroger distributes opioids to consumers within Ohio and Meigs County.

82. Defendant Wal-Mart Stores East LP ("Wal-Mart") is a Delaware Corporation with its principle place of business in Bentonville, Arkansas, doing business as Wal-Mart Pharmacy Warehouse #46. Wal-Mart is registered to do business in Ohio and distributes opioids to consumers within Ohio and Meigs County.

83. Defendant Miami-Luken, Inc. is an Ohio Corporation with its principal office located in Springboro, Ohio. Miami-Luken distributes opioids to consumers within Ohio and Meigs County.

84. Upon information and belief, Defendant AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware Corporation with its headquarters at 1300 Morris Drive, Chesterbrook, Pennsylvania, 19087.

85. Defendant Amerisource does substantial business as a pharmaceutical distributor to retail pharmacies and institutional providers in the Ohio and Meigs County.

86. Three of the Distributor Defendants, Cardinal, Amerisource, and McKesson are three of the largest opioid distributors in Ohio and Meigs County.

87. Defendant Brandon Worley is a resident and citizen of Ohio. At all relevant times, Defendant Worley was a sales representative in Ohio for Defendant Purdue. Defendant Worley promoted, sold and/or distributed OxyContin in Ohio, including prescribers and consumers within Meigs County and surrounding areas.

88. Defendant Donald Leathers is a resident and citizen of Ohio. At all relevant times, Defendant Worley was a sales representative in Ohio for Defendant Purdue. Defendant Worley promoted, sold and/or distributed OxyContin in Ohio, including prescribers and consumers within Meigs County and surrounding areas.

GENERAL FACTUAL ALLEGATIONS

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

89. The pain-relieving properties of opium have been recognized for millennia. Likewise, the magnitude of opium's potential for abuse and addiction has been well-known for ages and has led to its strict regulation world-wide. Opioids, similar to the illegal drugs opium and heroin, are substances that act on opioid receptors to produce morphine-like effects.

90. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, particularly on the battlefield, and they were popularly used in a wide variety of commercial products such as pain elixirs, cough suppressants, and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States,[37] and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly

[37] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

addictive nature.

91. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

92. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids: Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed a tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

93. In 1986, Dr. Russel Portenoy, M.D., who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[38]

94. Writing in 1994, Dr. Russel Portenoy, described the prevailing attitudes regarding the dangers of long-term use of opioids:

> ***The traditional approach to chronic non-malignant pain does not accept the long- term administration of opioid drugs.*** **This perspective has been justified by the perceived likelihood of**

[38] R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

> **tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.***[39]

According to Dr. Russel Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[40]

95. For all the reasons outlined by Dr. Russel Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them."[41]

96. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for

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[39] R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).
[40] *Id.*
[41] J. Loeser. Five crises in pain management, Pain Clinical Updates. 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety? 6 J. Pain Research 513, 514 (2013)).

months after a complete withdrawal from opioids, depending on how long the opioids were used.

97. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed, up to and including doses that are "frighteningly high."[42] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

98. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

99. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

100. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned,

[42] M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

"[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[43] The FDA required that, going forward, opioid makers of long-acting formulations clearly communicate these risks in their labels.

101. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[44]

102. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the 1990s when their deceptive marketing began.

B. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS

103. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have intentionally failed to disclose the substantial scientific evidence demonstrating that chronic opioid therapy actually worsens patients' health.

104. There are no controlled studies of the use of opioids beyond 16 weeks, and

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[43] Letter from Janet Roanecock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013) (emphasis in original).

[44] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed September 19, 2017).

no evidence that opioids improve patients' pain and function on a long-term basis. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

105. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[45]

106. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

107. Although opioids may work acceptably well during a limited, short period of time, long-term usage results in marked declines in patient's ability to function, their general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[46]

108. The foregoing is true both generally and for specific pain-related conditions. Studies of the long-term use of opioids for chronic lower back pain have failed to demonstrate an improvement in patients' function. Instead, research consistently shows

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[45] A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

[46] *See* A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

that long-term opioid therapy for patients who have lower back injuries does not permit patients to return to work or physical activity. This failure is due in part to addiction and other side effects.

109. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other, non-opioid medications.

C. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

110. Prior to the Defendants' marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used on a short-term, temporary basis in order to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those limited instances, the risks of addiction are considered low or of little significance.

111. By its very nature, the market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell their opioid products for both short term pain relief and for the treatment of long-term, chronic pain, they could achieve blockbuster levels of sales while exponentially increasing their profits. Further, Defendants recognized that the elevated risk of addiction associated with the long-term use of their highly-addictive, opioid products virtually guarantee that their blockbuster profits would continue indefinitely.

112. Defendants knew that to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. In other words, Defendants needed to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

113. Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors such as Plaintiff.

114. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort and pervert medical and public perception of existing scientific data.

115. As explained more fully herein, Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but patently false "consensus" supporting the long-term use of opioids.

D. DEFENDANTS USED "UNBRANDED" MARKETING TO EVADE REGULATIONS AND CONSUMER PROTECTION LAWS

116. Pharmaceutical companies' promotional activity can be branded or unbranded; unbranded marketing typically focuses on education regarding a particular

disease state or treatment rather than promoting a specific drug product. By using unbranded marketing in its communications, drug companies avoid the extensive regulatory framework governing branded communications.

117. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[47] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of prescribing those drugs to their patients.

118. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places additional restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[48] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[49] The term "accompanying" is interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug.[50] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

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[47] 21 U.S.C. 352(a); 21 CFR 202.1(e)(6); 21 CFR 202.1(e)(3); 21 CFR 1.21(a)
[48] 21 U.S.C 352(f); 21 U.S.C. 352(q); *U.S. v. Sullivan*, 68 S.Ct. 331, 335 (1948)
[49] 21 U.S.C.A. § 321(m)
[50] *Kordel v. U.S.*, 69 S. Ct. 106, 110 (1948)

119. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that a drug's marketing materials are misleading, it can issue either an untitled letter or a warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

120. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Defendants intentionally avoided branded promotional materials for the express purpose of escaping regulatory review of their claims.

121. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated and unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

122. By acting through third parties, Defendants were able to give the false appearance that their messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company pieces.

123. As part of their marketing scheme, Defendants spread and validated their

deceptive messages through the following unbranded vehicles ("the Vehicles"): (i) so-called "key opinion leaders" (*i.e.*, Physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported scientific literature, ghostwritten by Manufacturer Defendants and published by KOLs ; (iii) treatment guidelines ghostwritten by Manufacturer Defendants and published as a direct result of KOLs reputation and involvement with the publishing organizations, which were distributed within Meigs County causing injury within the County; (iv) CMEs by KOLs, deliberately conducted within Ohio, attended by physicians in Meigs County, causing tortious injury within the County; and (v) unbranded patient education materials disseminated within Ohio and Meigs County through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which were deliberately influenced by Defendant-controlled KOLs, exercising their influence both directly and indirectly because they served in leadership roles in these organizations.

124. Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

125. Even where such unbranded messages were disseminated through third-party Vehicles, including the KOLs, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials all Defendants knew were false, misleading, unsubstantiated, unbalanced, and incomplete from the very outset of the message's "creation" by the purportedly independent KOLs. As described herein, Defendants' sales representatives distributed third-party marketing material to

Defendants' target audience that was deceptive.

126. Defendants took an active role in writing, guiding, reviewing, and approving many of the misleading statements issued by third parties, including the KOLs' statements, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain. The process described in this paragraph is commonly referred to as "Ghostwriting."

127. The unbranded marketing materials that Defendants assisted in creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks. All of these unbranded marketing materials were promoted by the KOLs falsely from the very outset as independent statements. The KOLs' false promotion of independence provided the unbranded marketing materials utilized by Manufacturer Defendants the credibility required to fraudulently induce physicians within Ohio and Meigs County to prescribe opioids for chronic pain.

a. *Manufacturer Defendants' Misuse of KOLs*

128. The Manufacturer Defendants cultivated a select circle of doctors who were chosen and sponsored by Manufacturer Defendants solely because they promoted the aggressive treatment of chronic pain with opioids in return for the payment of vast sums of money by the Manufacturer Defendants. Pro-opioid KOLs have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid KOLs have written, consulted on, edited, and lent their names to books and

articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through the KOLs, each of whom accepted money to promote the false marketing claims of Defendants.

129. In return for their successful pro-opioid advocacy, KOLs received money, prestige, recognition, research funding, and avenues to publish. The more successful the KOLs' deceptive promotion of Opioids for Chronic Pain, the more they were able to receive from the Manufacturer Defendants.

130. Defendants cited and promoted the KOLs and studies or articles by the KOLs to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications of truly independent doctors critical of the use of chronic opioid therapy.

131. Defendants carefully vetted their KOLs to ensure that they would remain on-message and supportive of the agenda to falsely promote Opioids as safe for the treatment of Chronic Pain. Defendants also kept close tabs on the content of the materials published by the KOLs, if not authoring, editing, and/or revising them in their entirety prior to publication.

132. In their promotion of the use of opioids to treat chronic pain, the KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit the Defendants.

b. *Defendants' Corruption of Scientific Literature through KOLs*

133. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants, instrumentally relying on KOLs, misled physicians, patients, and health care payors into believing that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long- term opioid use outweighed the risks.

134. To accomplish their goal, Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals authored by KOLs.

135. Defendants' plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants' marketing departments and with Defendants' marketing and public relations consultants, ultimately being published and promoted by KOLs.

136. In these materials, Defendants (and their KOL surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

137. Defendants also made sure that favorable articles were disseminated and

cited widely in the medical literature and by KOLs, even when Defendants knew that the articles distorted the significance or meaning of the underlying study. Most notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"), in a manner that makes it appear that the item reported the results of a peer reviewed study. It also cited two CME programs sponsored by Endo where KOLs were presenters. Defendants and the KOLs acting on their behalf failed to reveal that this "article" was actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

138. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations,

not chronic pain, making the data useless for any generalization regarding the safety or efficacy of opioids for treating chronic pain. Even aside from chronic pain treatment, the letter notes that when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were followed, for how long. None of these serious limitations were disclosed when Defendants and KOLs acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

139. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has.

140. Defendants not only created and promoted favorable studies in the literature through the paid efforts of KOLs but, in order to discredit or suppress negative information, funded studies and articles that targeted articles contradicting Defendants' claims or raising concerns about chronic opioid therapy. In order to do so, Defendants, often with the help of KOLs, used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

141. Defendants' strategy—to create, fund, plant, and promote supportive literature for citation as pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted their claims—was flatly inconsistent with their legal obligations. Defendants' strategy was intended to alter, and did alter, prescribing and consumer patterns, including those in Meigs County, by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

c. *Defendants' Misuse of Treatment Guides*

142. Treatment guidelines authored with KOLs' influence but under the direction and control of Manufacturer Defendants have been particularly important in securing acceptance for chronic opioid therapy. The guidelines are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

i. FSMB

143. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

144. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 edition of the guidelines, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught that opioids were "essential" for the treatment of chronic pain, including as a first prescription option, rather than that opioids could be appropriate in limited cases after other treatments had failed. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians

nationwide, including in Meigs County.

145. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including those in Meigs County.

146. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications."

147. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by a KOL named Dr. Scott Fishman, M.D. Dr. Fishman was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

148. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman's work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

149. Defendants relied on 1998 Guidelines to convey the alarming message that

"under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

ii. AAPM/APS GUIDELINES

150. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[51] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was a KOL named Dr. Russel Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

151. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, M.D., received support from Defendants Janssen, Cephalon, Endo, and Purdue.

152. The 2009 Guidelines promote opioids as "safe and effective" for treating

[51] Haddox J., et al., The Use of Opioids for the Treatment of Chronic Pain – A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 6(1) Pain Forum 77-79 (1997)

chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in Meigs County during the relevant time period, and were and are available online.

153. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

iii. GUIDELINES THAT DID NOT RECEIVE DEFENDANTS' SUPPORT

154. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines (the authors of which did not accept drug company funding) reached very different conclusions.

155. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous

adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[52]

156. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[53]

157. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[54]

d. *Defendants' Misuse of CMEs*

158. A CME (an acronym for "Continuing Medical Education") is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. With the support of Defendants, the KOLs become highly respected in their fields. As a result, they typically

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[52] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

[53] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

[54] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf (accessed September 19, 2017).

teach CMEs. The program is thought to be an independent, objective reflection of these physicians' medical expertise. As a result, CMEs can be especially influential with doctors. In fact, the Defendants used KOL-taught CMEs in Ohio to influence the prescribing habits of doctors within Ohio and Meigs County, ultimately inducing Meigs County to provide health insurance for its workforce and treatment to its citizens that allowed the prescribing of opioids for chronic pain, ultimately costing lost revenue.

159. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants, through KOLs, aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

160. Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

161. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education

subject matter."[55]

162. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski, M.D., and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.[56] It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer or non-cancer related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," Actiq, and "fentanyl buccal table," Fentora, including in patients with chronic non-cancer pain. Dr. Miaskoski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speaker's bureau.[57] Dr. Fine also received funding from Cephalon for consulting services.

163. Physicians in Meigs County attended or reviewed Defendants' sponsored CMEs during the relevant time period and were misled by them.

164. By sponsoring CME programs put on by Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) like APF, AAPM and others, Defendants could rely upon instructors to deliver messages favorable to them, as these organizations were dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and

[55] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).
[56] Fine, Perry, et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News (2009), https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (accessed December 29, 2017).
[57] 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. *Defendants' Misuse of Patient Education Materials and Front Groups*

165. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[58] Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[59] Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

166. Defendants entered into arrangements with numerous Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) to promote the prescription of opioids for the treatment of chronic pain. Each one of these Front Groups depends largely, if not exclusively, upon Defendants for significant funding and, in some cases, depend wholly upon Defendants' funding for their continued survival. In addition to generating Defendants' promotional materials and programs supporting chronic opioid therapy to be provided to doctors and patients, the Front Groups also assisted Defendants' marketing efforts by responding to negative articles and advocating against

[58] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

[59] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on the use of opioids to treat chronic pain. Defendants created a symbiotic relationship with the Front Groups whereby Defendants funded them in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages. In turn, the supportive messages drove prescriptions and profits for Defendants and ensured continued funding of the Front Groups.

i. AMERICAN PAIN FOUNDATION

167. The most prominent and effective of Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

168. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain treatment and minimized their risks, specifically the risk of addiction. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of Meigs County.

169. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

170. While APF held itself out as an independent patient advocacy organization, it simultaneously engaged in grassroots lobbying against various legislative initiatives that might regulate the prescription of opioids and protect patients from the risks associated with the unnecessary prescription of highly addictive and ineffective drugs. In stark contrast to its stated purpose, APF functioned principally as an advocate for the interests of Defendants, not patients.

171. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Defendants. APF also assisted in marketing projects for Defendants.

172. The intimate relationship between APF and Defendants demonstrates APF's clear lack of independence in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages strongly indicates that each Defendant that provided it with funding was able to exercise editorial control over its publications.

173. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links - financial and otherwise - between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately,"[60] proving the degree of its dependence upon Defendants' financing as well as their control over it.

ii. THE AMERICAN ACADEMY OF PAIN MEDICINE

[60] William Heisel, USC Annenberg Center for Health Journalism, Antidote: Investigating Untold Health Stories, *Journalists Bag a Big One: The American Pain Foundation*, https://www.centerforhealthjournalism.org/blogs/2012/05/14/journalists-bag-big-one-american-pain-foundation (accessed September 19, 2017).

174. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to Defendants' deceptive marketing scheme.

175. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

176. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids: 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs, Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Lynn Webster, M.D. was elected president of AAPM while under a DEA investigation. Another past AAPM president, KOL Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."[61]

177. AAPM's staff understood that they and their industry funders were engaged

[61] *Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine*, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed September 19, 2017).

in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

E. DEFENDANTS ACTED THROUGH KOLs AND FRONT GROUPS TO CREATE, PROMOTE, AND CONTROL UNBRANDED MARKETING

178. Like the tobacco companies that engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the industry-funded and directed Front Groups and KOLs to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superior efficacy of opioids to treat chronic pain.

179. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Despite knowing that this information was false and misleading, Defendants, Front Groups, and KOLs disseminated these misrepresentations nationwide, including to Meigs County prescribers and patients.

180. One Vehicle for Defendants' marketing collaboration was the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

181. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American

Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations - almost all of which received substantial funding from Defendants.

182. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[62] This was critical because a REMS that went too far in narrowing the uses or benefits or in highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts and adversely affect profits. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, rather than undermine, their deceptive marketing of opioids for chronic pain treatment.

F. DEFENDANTS' MISREPRESENTATIONS

183. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in Meigs County. These promotional messages were intended to and did encourage patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.

[62] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

184. Recognizing that doctors are the gatekeepers for controlling access to prescription drugs, not surprisingly, Defendants focused the bulk of their marketing efforts and multi-million dollar budgets on the professional medical community. As a controlled substance with significant regulatory barriers limiting access, Defendants knew doctors would not prescribe opioids to patients with common chronic pain complaints unless doctors were convinced that opioids had real benefits and minimal risks. Accordingly, Defendants concealed from prescribers, patients, and the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Instead, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, Meigs County doctors began prescribing opioids on a long-term basis to treat chronic pain, a treatment choice that most (if not all) never would have considered prior to Defendants' campaign.

185. Drug company marketing materially impacts doctors' prescribing behavior.[63] Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs. Evidence shows that doctors who would otherwise not have prescribed opioids were, in fact, induced by Defendants' deceptive marketing to prescribe opioids for chronic pain as a result of Defendants' deceptive marketing.

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[63] See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

186. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, 88% of the practitioner respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities.[64] These results are the direct consequence of Defendants' fraudulent marketing campaign.

187. As described in detail below, Defendants:

- Misrepresented the truth about how opioids lead to addiction;
- Misrepresented that opioids improve function;
- Misrepresented that addiction risk of opioids can be managed;
- Misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- Falsely claimed that withdrawal is simply managed;
- Misrepresented that increased doses pose no significant additional risks to patients;
- Falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

188. Defendants' misrepresentations were aimed at doctors, patients, and payors.

189. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants'

[64] Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.[65]

a. *Defendants, Acting Individually and Collectively, Misrepresented the Truth About How Use of Opioids Leads to Addiction.*

190. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, and aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and persuaded them that opioid addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for chronic pain. As both an intended and foreseeable result, doctors in Meigs County prescribed more opioids to more patients, thereby enriching Defendants.

191. Each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, despite the complete lack of supporting scientific evidence.

192. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which fraudulently claimed that addiction is rare and limited to extreme cases of unauthorized dose escalations, opioid prescription fraud, or theft.

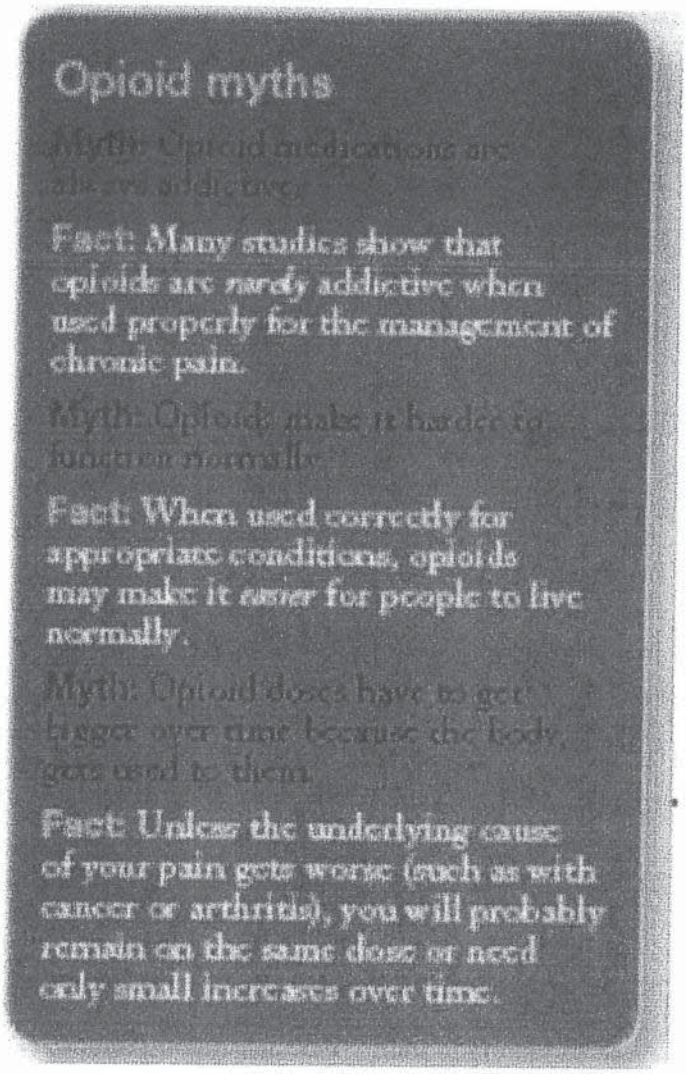
193. Similarly, Endo sponsored a website, www.painknowledge.com, through APF, which falsely claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the

[65] Letter from Janet Roanecock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician.

194. Additionally, Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for *genuine* pain will not become addicted, a claim which is both unsupported and known to be false.

195. Likewise, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which, as set forth in the excerpt below, described the fact that opioids are addictive as a "myth" and falsely asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."



Although the term "rarely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician, which is untrue. The guide states as a "fact" that "[m]any studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

196. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to

become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial.

197. For another example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.[66] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

198. In addition, in the 1990s, Purdue amplified the pro-opioid message with promotional videos featuring Dr. Portnoy and other doctors in which it was claimed, "the likelihood that treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[67]

199. As yet another example from the industry, Actavis's strategy and pattern of deceptive marketing is similarly evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages described above—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Meigs County.

200. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on

[66] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[67] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (accessed September 19, 2017).

chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have necessitated increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to inform doctors, via its sales representatives, of the greater risks associated with opioids at high doses.

201. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers before that date. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]." Certain risks that the FDA noted were misrepresented include the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."

202. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients, regardless of past abuse histories, amongst other deceptive statements as described above.

203. Mylan Pharmaceuticals made payments to APS to spread misinformation and deceive the public into thinking that opioids were safe to use for treating chronic pain, although the company dismisses its involvement and overall payment amount by criticizing a Senate inquiry as politically motivated. Mylan donated approximately $20,000 to APS (roughly .02% of total donated).[68]

204. Mylan made its first donation of $15,000 in March 2015, at the same time it launched intermediate dosage strengths for its fentanyl transdermal system, which it characterized as "marketing efforts to educate doctors about the availability of the intermediate strengths."[69] Mylan very clearly sought a return on its investment in APS.

205. At the same time Mylan downplays its involvement, it seized the opportunity created by APS and the other Defendants to market its top selling Fentanyl patch for "persistent, moderate-to-severe chronic pain."[70] According to reports, Mylan's generic fentanyl patch has become popular for drug abusers in Ohio as it does not show up in employment drug tests. The patch is designed to slowly release over 72 hours, but

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[68] U.S. Senate Homeland Security & Governmental Affairs Committee Minority Staff Report, *Fueling and Epidemic: Report Two Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups,* https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (published February 12, 2018, accessed March 30, 2018).

[69] *Id.*

[70] Vermes, Krystle, *Mylan Expands Generic Fentanyl Patch Doses*, http://www.pharmacytimes.com/product-news/mylan-expands-generic-fentanyl-patch-doses (published March 12, 2015, accessed March 30, 2018).

drug users have found that cutting it up and placing it in their lips, like chewing tobacco, or adhering a patch cut in half onto their cheeks releases the fentanyl much more quickly.[71] One case report in the published medical literature recounts a drug overdose that resulted from intravenous injection of fentanyl extracted by boiling a Mylan fentanyl patch.[72]

206. Mylan knew or should have known about the misuse of its Fentanyl since July 15, 2005, when the FDA issued a Public Health Advisory on the subject. In the advisory, the FDA noted that the FDA had been "examining the circumstances of product use to determine if the adverse events may be related to inappropriate use of the patch."[73] Mylan has not only profited from causing addiction, but it profits from the addiction itself by selling generic methadone and buprenorphine as well.

207. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who prescribed long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that "exaggerated" concerns about the risk of addiction resulted in patients' pain being under-treated while opioids were over-regulated and under-prescribed. The Treatment Options

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[71] Swint, Jack, *Mylan Fentanyl Patch New Choice of Drug to Abuse*, http://westvirginianews.blogspot.com/2012/04/mylan-fentanyl-patch-new-choice-of-drug.html (published April 7, 2012, Accessed March 30, 2018).

[72] Schauer, Cameron, et al., *The Fentanyl Patch Boil-Up – A Novel Method of Opioid Abuse*, https://onlinelibrary.wiley.com/doi/pdf/10.1111/bcpt.12412, (accepted April 14, 2015).

[73] Food and Drug Administration, Center for Drug Evaluation and Research, https://wayback.archive-it.org/7993/20170723140807/https://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/EnforcementStoryArchive/UCM091066.pdf (accessed April 11, 2018).

guide funded by Purdue and Cephalon claims that "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."[74]

208. *Let's Talk Pain*, sponsored by APF, AAPM and Janssen, likewise warns, "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients.... This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

b. *Defendants, Acting Individually and Collectively, Misrepresented that Opioids Improve Function*

209. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

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[74] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

210. Although opioids may initially improve patients' function by providing pain relief in the short term, no controlled studies of the use of opioids beyond 12 weeks has ever shown that opioids improve patients' function in the long-term. On the contrary, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[75] Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

211. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[76]

212. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo and Purdue, deceptively taught that relief of pain in itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

213. Cephalon and Purdue sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (*e.g.*, Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF

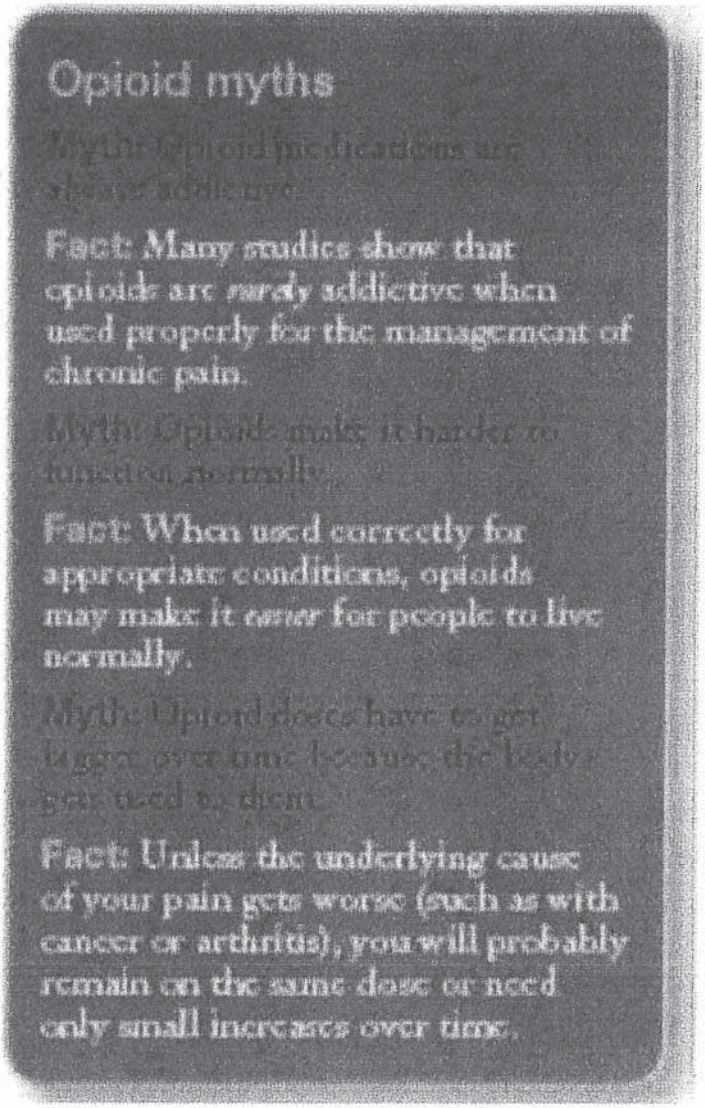
[75] Jeffrey Dersh, et al., Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, 33(20) Spine 2219-27 (Sept. 15,2008).
[76] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA21-260 (March 24, 2008).

distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently still available online.

214. Through the APF, Endo sponsored a website, painknowledge.com, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.

215. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA, and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

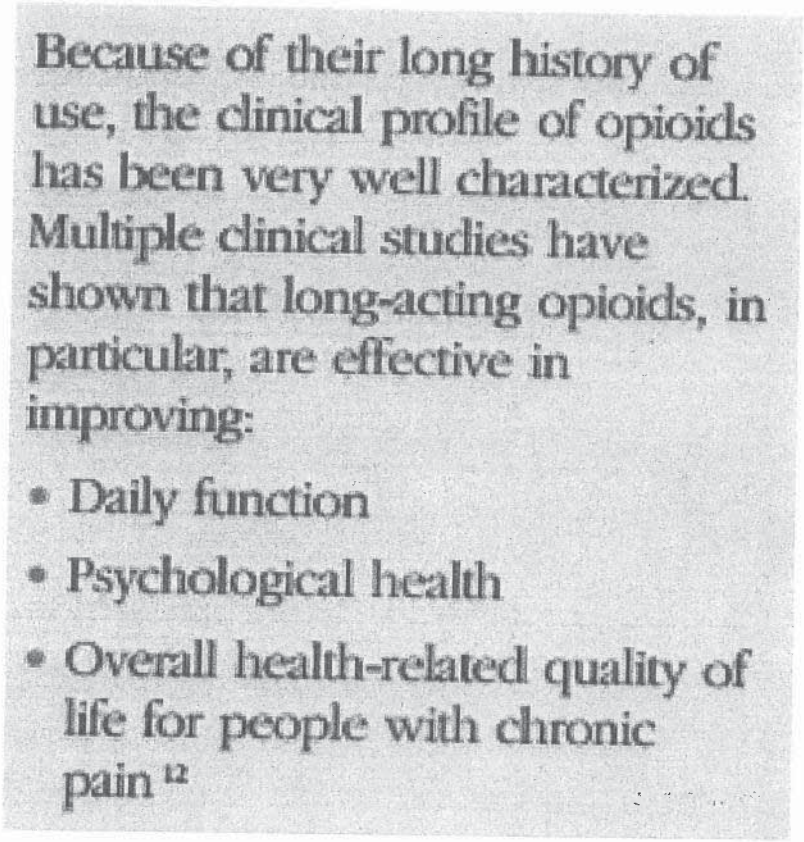
216. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.



217. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative despite the lack of statistical support.

218. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain* &

Its Management (2011), which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement.



Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain [12]

The sole reference for the functional improvement claim 1.) noted the absence of long-term studies and 2.) actually stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

219. Purdue sponsored and Janssen provided grants to APP to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning."

c. *Defendants, Acting Individually and Collectively, Misrepresented that Addiction Risk can be Effectively Managed*

220. Defendants each continue to maintain to this day that most patients can safely take opioids long-term for chronic pain relief without becoming addicted. Presumably to explain to doctors the high incidence of patient opioid addiction, Defendants have recently acknowledged that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they claim, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) and allow doctors to more closely monitor patients at greater risk of addiction.

221. There are three fundamental flaws in Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that the addiction risk screening tools currently available are reliable, effective, capable of being applied correctly and consistently, or invulnerable to patient manipulation. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through the screening tools can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients identified through such screening tools as "low risk" can take opioids long-term without significant danger of addiction.

222. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments,

opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[77] Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening tests are not proven to work in the real world, even when the most well-intentioned doctors were misled to employ them.[78]

223. Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011–2012 narcotic prescription data of the type regularly used by Defendants to market their drugs, that only 385 of the more than half million prescribers of opioids during that time period were identified as pain specialists.[79]

224. In materials they produced, sponsored, or distributed, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain.

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[77] The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

[78] M. Von Korff, et al., *Long-term opioid therapy reconsidered*, 15595, Annals Internal Med. 325 (Sept. 2011); L. Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).

[79] Express Scripts Lab, A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain (December 2014).

Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring – with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiff. This, of course, led to a "heads you lose; tails you lose" outcome for patients (all of whom are subjected to an unacceptable risk of addition) and for payors, including Plaintiff.

225. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

226. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by KOL Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

d. *Defendants, Acting Individually and Collectively, Misled Physicians,*

Patients, and Payors Through the Use of the Term "Pseudoaddiction"

227. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by KOL Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction" – as if patients could not experience both.

228. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

229. Cephalon and Purdue sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

230. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President; nor did Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."[80]

231. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid*

[80] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain 363 (Mar. 1989).

Prescribing on its unbranded website, PartnersAgainstPain.com, in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but rather was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated . . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

e. *Defendants, Acting Individually and Collectively, Claimed Withdrawal is Simply Managed*

232. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—an adverse effect that also makes it less likely that patients will be able to stop using drugs.

233. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

234. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid

dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days—when it is even successful at all.[81]

235. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

f. *Defendants, Acting Individually and Collectively, Misrepresented that Increased Doses Pose no Significant Additional Risks*

236. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

237. In materials Defendants produced, sponsored or controlled, Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

238. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ

[81] See Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.[82]

239. Cephalon sponsored a CME written by KOL Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

240. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

241. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. ... You won't 'run out' of pain relief."

242. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

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[82] Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

243. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

g. *Defendants, Acting Individually and Collectively, Deceptively Omitted or Minimized the Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment*

244. In materials they produced, sponsored, or controlled, Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

245. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[83] hormonal dysfunction;[84] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[85] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder

[83] Letter from Janet Roanecock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).
[84] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).
[85] Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study, Eur. J. Pub. H. (July 31, 2014).

and anxiety also often accompany chronic pain symptoms.[86]

246. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.[87] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

247. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

248. Janssen and Purdue sponsored and Endo provided grants to APF to distribute *Exit Wounds* (2009), which omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

249. As a result of Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6%

[86] Karen H. Seal, Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan, 307(9) J. Am. Med. Ass'n 940- 47 (2012).
[87] Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[88]

G. DEFENDANTS' PROMOTION OF THEIR BRANDED DRUGS WAS ALSO DECEPTIVE

250. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in Meigs County. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

251. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors' prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials

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[88] M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51*(10)* Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

described above throughout the United States, including to doctors in Meigs County.

H. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS AND WOULD HARM PLAINTIFF AND ITS RESIDENTS

252. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

253. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

254. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid

use, addiction, injury, and death.

I. DEFENDANTS FRAUDULENTY CONCEALED THEIR MISREPRESENTATIONS

255. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

256. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.

257. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did not support. The true lack of support for Defendants' deceptive messages was not apparent to the vast majority of the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or its residents.

258. Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

259. Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now assert. Plaintiff did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through the public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put them on notice of potential claims.

J. DISTRIBUTOR DEFENDANTS INTENTIONALLY FAILED TO TAKE ANY ACTION TO STOP THE MISUSE OF OPIOIDS, IN VIOLATION OF STATE AND FEDERAL LAWS AND REGULATIONS

260. The Distributor Defendants purchased opioids from manufacturers, such as the named Manufacturer Defendants herein, and sold them to pharmacies throughout Pleasants County and Ritchie County.

261. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Meigs County.

262. Ohio state law imposes a duty upon the Defendant Wholesale Distributors and Manufacturer Defendants to provide effective controls and procedures to guard against theft and diversion of controlled substances. Ohio Administrative Code, Section 4729-9.

263. Ohio state law imposes a duty upon the Defendant Wholesale Distributors and Manufacturer Defendants to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the Ohio Board of Pharmacy of

suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Id.

264. Federal regulations similarly impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

265. The "suspicious order" criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

266. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See SouthRoane*

3Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

267. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[89]

268. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[90]

269. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[91]

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[89] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[90] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

[91] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin.,

270. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[92]

271. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[93] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[94] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[95]

272. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[96] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[97] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of

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U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[92] *See* Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[93] Rannazzisi Letter, *supra*, at 2.

[94] *Id.* at 1.

[95] *Id.* at 2.

[96] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185- RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[97] *Id.*

completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is

> actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[98]
>
> Finally, the DEA letter references the Revocation of Registration issued in *SouthRoane Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[99]

273. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[100]

274. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set

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[98] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), *Supra.*

[99] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), *Supra.*

[100] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *2 [hereinafter Brief of HDMA].

forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[101]

275. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

276. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[102]

277. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's community, is excessive for the medical need of the community and facially suspicious; some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably

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[101] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

[102] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

claim ignorance of them.[103]

278. Additionally, the Distributor Defendants' grossly negligent distribution to pharmacies outside the County also caused an influx of illicit diversion of opioids within Meigs County.

279. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

280. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders that deviated substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants could foreseeably anticipate that opioids were likely to be diverted to Plaintiff's Community.

281. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

282. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

283. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and

[103] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

failed to inform the authorities including the Ohio Department of Health of suspicious orders when discovered, in violation of their duties under federal and state law.

284. The Distributor Defendants failed to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[104]

285. The federal and state laws at issue here are public safety laws.

286. The unlawful conduct by the Distributor Defendants is purposeful and intentional.

287. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

288. The Distributor Defendants acted with actual malice, have consciously disregarded the rights and safety of other persons, and said actions have caused substantial harm.

289. The Distributor Defendants' repeated shipments of suspicious orders over an extended period, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

290. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding the

[104] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

Distributor Defendants' compliance with their legal duties.

291. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a) The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[105]

b) The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[106]

c) The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[107]

d) The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[108]

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[105] Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4–5.
[106] Brief for HDMA and NACDS, *supra*, 2016 WL 1321983 at *8.
[107] *Id.* at *14
[108] *Id.* at *22

e) The Associations alleged (inaccurately) that "DEA's regulations [sensibly impose] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[109]

f) Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[110]

292. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[111]

293. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218-219, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

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[109] *Id.* at *24-25
[110] *Id.* at *26
[111] *See* Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

294. Wholesale Distributor McKesson was recently forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[112]

295. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[113] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers" including the McKesson Distribution Centers located in 12 different locations, any of which could have foreseeably caused the diversion of opioids into Meigs County.[114] Due to these violations,

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[112] Department of Justice, Administrative Memorandum of Agreement, January 17, 2017, https://www.justice.gov/opa/press-release/file/928476/download, (accessed October 27, 2017).
[113] Department of Justice, *Administrative Memorandum of Agreement* at 4, *Supra.*
[114] *Id.*

McKesson agreed that its authority to distribute controlled substances from these 12 facilities would be partially suspended.[115]

296. As punishment for its wrongdoing, McKesson agreed to pay a $150 million fine and suspend the sale of controlled substances from distribution centers in several states.[116]

297. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[117] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed in its obligations.[118] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[119]

298. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

299. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office

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[115] *Id.* at 6.
[116] *Id.* at 8.
[117] *Id.* at 4.
[118] *Id.*
[119] *Id.*

of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[120] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[121] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford

[120] U.S. Dep't of Justice, Evaluation and Inspections Div., Office of the Inspector Gen., *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf, (accessed October 27, 2017).
[121] *Id.*

Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against facilities it owned in South Carolina, Florida, New York, and Washington.

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

300. Defendant Rite Aid agreed that it failed to comply by State and Federal requirements after a pattern of failing to meet its duty was discovered by the Department of Justice.[122] In January 2009, Rite Aid Corporation and Subsidiaries agreed to pay $5 million in civil penalties to resolve violations in eight states of the Controlled Substances Act. Nonetheless, Rite Aid continues to dispense opioids in quantities significantly higher than medically necessary to residents of Nobel County.

301. Defendant CVS has paid over $40 million in fines as the result of opioid prescription investigations by the DEA and the United States Department of Justice. Yet CVS continues to dispense opioids in quantities significantly higher than medically necessary to residents of Meigs County. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the Department of Justice that its stores and pharmacists had been violating their duties under the Controlled Substances Act, by filling prescriptions with no legitimate medical purpose.[123] CVS has settled similar cases with Florida, Oklahoma, Massachusetts, New Hampshire, and Rhode Island, for filling forged prescriptions for addictive painkillers and filling prescriptions with no legitimate medical purpose.

302. Operating within Ohio and Meigs County, the Distributor Defendants must have neglected their duties given that 23.2 retail prescriptions were dispensed per 100 residents.[124] The total allows for one full prescription for each man, woman, and child within the County.

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[122] Department of Justice, *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act*, https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (Published January 12, 2009).

[123] Press Release, Drug Enf't Admin., DEA Reaches $8 million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016.) https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled (Accessed February 20, 2018).

[124] Centers for Disease Control, *U.S. County Prescribing Rates*, https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (2016)

303. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[125]

304. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

305. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[126] Given the sales volumes and the company's history of violations, this

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[125] Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.61697ec67e05; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.014176059151; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, http://www.100daysinappalachia.com/2017/02/22/dea-agent-no-leadership-west-virginia-amid-flood-pain-pills/, Charleston Gazette-Mail, Feb. 18, 2017, (all accessed October 27, 2017).

[126] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-

executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results in favor of profits.

306. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[127] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

307. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

308. In fact, when drug distribution executives were summoned to testify before a House Energy and Commerce Committee Oversight Panel on May 8, 2018, executives for Cardinal Health, AmerisourceBergen, McKesson and H.D. Smith denied that their companies contributed to the opioid crisis.

309. Meanwhile, the opioid epidemic rages unabated in the nation, the State of Ohio, and in Plaintiff's community.

310. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor

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the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.6d9936e87c93, (accessed October 27, 2017).

[127] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.0b845f727e2c, (accessed October 27, 2017).

Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Meigs County and elsewhere, harming Plaintiff.

311. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped significant doses of highly addictive controlled opioid pain killers into Meigs County and elsewhere, causing diversion of opioid pain killers within Meigs County.

312. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

313. The sheer volume of the increase in opioid pain medications, including oxycodone, being distributed to retailers, should have put the Distributor Defendants on notice to investigate and report such orders.

314. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Meigs County and elsewhere.

315. Upon information and belief, the Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Meigs County from 2007 to the present.

316. The Defendant Distributors knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Meigs County.

317. The Defendant Distributors also paid their sales force bonuses and

commissions on the sale of most or all of the highly addictive opioid pain medications within Meigs County.

318. The Distributor Defendants made substantial profits from the opioids sold in Meigs County and elsewhere.

319. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the residents of Meigs County.

320. By the actions and inactions described above, the Distributor Defendants caused great harm to Meigs County.

321. The Distributor Defendants have abandoned their duties imposed under federal and state law; taken advantage of a lack of DEA law enforcement; and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

K. DESPITE KNOWING ABOUT THE RISK OF ADDICTION, MISUSE, AND ABUSE TO THE COUNTY AND OHIO, THE SALES REPRESENTATIVE DEFENDANTS MISREPRESENTED THE SAFETY OF OPIOIDS FOR TREATING CHRONIC PAIN TO PHYSICIANS

322. At all relevant times, Defendant Worley was a Purdue representative in Ohio and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in Ohio, including to those who prescribed and/or consumed the drug in the County and across the state.

323. The Sales Representative Defendants owed a duty of care to Plaintiff in the marketing, advertising, sale, and promotion of Purdue's highly dangerous, addictive and abuse-prone OxyContin.

324. The Sales Representative Defendants owed Plaintiff a duty to use reasonable care because, *inter alia*, it was foreseeable, and in fact known to Sales Representative Defendants that their conduct would result in injuries and damages to and

within the County.

325. The Sales Representative Defendants were aware that OxyContin posed a risk of harm to Ohio and Meigs County, including its risks relating to addiction, abuse, and diversion, all of which were occurring and ongoing in the County and across the state.

326. The Sales Representative Defendants had actual knowledge that the safety, efficacy, addictiveness, abuse and diversion potential of OxyContin was negligently and recklessly marketed, advertised, promoted, and sold.

327. The Sales Representative Defendants knew that OxyContin was highly susceptible to addiction, misuse, abuse and/or diversion and the risk for each of these factors bore a direct relationship to the amount and volume of opioids being prescribed within Ohio and Meigs County, and in fact that Oxycontin was being misused, abused and diverted across the country, including within Meigs County and across Ohio, for example:

a) The Sales Representative Defendants witnessed first-hand the devastating effects of OxyContin in and around Ohio and Meigs County that OxyContin was being regularly abused, misused, and diverted;
b) The Sales Representative Defendants were informed, alerted, questioned, and/or made aware by prescribers throughout Ohio and Meigs County that OxyContin was being abused, misused, and diverted and, on at least one occasion, that a family member of a prescriber within Ohio had overdosed on OxyContin in Ohio;
c) Memos from sales representatives within Ohio and/or surrounding areas were distributed and/or discussed between Purdue employees and representatives, including Defendant Worley, which contained "red flags" about OxyContin and detailed reports from prescribers that their patients were misusing, abusing, and diverting OxyContin; and
d) Defendant Worley was made aware of medical literature and studies that concluded OxyContin was more attractive to drug abusers compared to other prescription pain pills.

328. The Sales Representative Defendants knew or should have known that

OxyContin was unreasonably dangerous and highly addictive and highly susceptible to abuse and diversion, yet knowingly and negligently provided false and/or misleading information to prescribers within Ohio, including Meigs County and Ohio, concerning the risk of addiction, abuse and diversion of OxyContin and of its relative safety.

329. The Sales Representative Defendants also represented to prescribers throughout Ohio and Meigs County that OxyContin was safe for use in chronic pain patients.

330. Upon information and belief, the Sales Representative Defendants purposefully or negligently caused the flooding of communities across Ohio, including Meigs County, with highly dangerous and addictive opioids knowing that these drugs were being misused, abused and diverted.

331. The Sales Representative Defendants knew or should have known that opioid addiction, abuse and/or diversion and their related consequences would injure and damage communities across the country including Meigs County. As discussed herein, applicable Ohio laws, and the industry standards applicable to the manufacture, advertising, labeling, distribution. and sale of opioid drugs exist to control addiction, abuse and/or diversion associated with these dangerous drugs. Moreover, the Sales Representative Defendants were aware their actions and the effects their actions were having in communities across the country, including Meigs County. The escalating amounts of highly addictive drugs being prescribed and distributed, and the sheer volume of these prescription opioids, further alerted the Sales Representative Defendants that addiction was fueling increased addiction, abuse and diversion, and that legitimate medical purposes were not being served.

332. Despite this knowledge, and in direct disregard for the known and foreseeable harms to Plaintiff, the Purdue Sales Representative Defendants negligently and recklessly breached their duty to Plaintiff by, but not limited to:

a) Negligently and recklessly marketing, advertising, and promoting OxyContin in Meigs County and surrounding areas;
b) Misrepresenting and misstating the addiction, abuse and/or diversion potential of OxyContin;
c) Overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
d) Downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
e) Overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
f) Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
g) Marketing OxyContin for indications and benefits that were not supported by substantial evidence; and,
h) Misrepresenting to health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

333. At all times material herein, the Sales Representative Defendants willingly and knowingly participated in Defendant Purdue's deceptive and misleading marketing scheme, were aware of its existence, and did nothing about it. The Purdue Sales Representative Defendants promoted, perpetuated, and furthered Purdue's deceptive and misleading marketing campaign by knowingly falsely promoting and marketing OxyContin as less addictive and less subject to abuse and diversion than other opioids.

334. The Purdue Sales Representative Defendants had a financial incentive to knowingly provide false information to prescribers within Ohio and Meigs County and their pay and continued employment depended on the volume of sales and prescriptions

written within their District and surrounding areas. Upon information and belief, the Sales Representative Defendants received extremely lucrative bonuses (some in the hundreds of thousands of dollars), trips, and other items of value as a result of their success in pushing OxyContin into the communities of Ohio.

335. On information and belief, utilizing Purdue and the Manufacturer Defendant's deceptive marketing as further detailed herein, Defendant Sales Representatives sold opioids for Purdue in Ohio.

336. Sales Representative Defendants knew their marketing and the information they and their sales team provided was a substantial factor in physicians, patients, and others prescribing, purchasing or using opioids in Ohio and Meigs County.

337. At all times material herein, prescribers and consumers within Ohio and in Meigs County relied upon the representations made by Sales Representative Defendants and their reliance was justified.

338. As stated herein, Defendants' breach of duty bears a causal connection with and/or proximately resulted in the harm and damages to the Plaintiff.

339. As a direct and proximate result of Purdue Sales Representative Defendants' actions, as set forth herein, Plaintiff have suffered and continue to suffer injury and damages, including but not Limited to, incurring excessive costs related to diagnosis, treatment, and cure of abuse and/or. addiction or risk of addiction to opioids; bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement associated with opioid addiction, abuse and diversion; and property damage.

CLAIM ONE
CONSUMER SALES PRACTICES
CHAPTER 1345 OHIO REVISED CODE
(AGAINST ALL DEFENDANTS)

340. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

341. At all times relevant to this Complaint, Defendants were engaged in the trade or commerce of manufacturing, marketing, selling, and/or distributing prescription opioid pain medications. For 20 years, Defendants have been the leading force in the prescription opioid market, both nationwide and in Ohio.

342. By engaging in the acts and practices alleged herein, Defendants made or caused to be made to Ohio consumers, directly or indirectly, explicitly or by implication, misrepresentations that, reasonably interpreted, are material, false, and likely to mislead.

343. Defendants violated the Ohio Consumer Sales Practices Act ("CSPA"), R.C. 1345.01, *et seq.* because they engaged in deceptive acts or practices in the conduct of business, trade or commerce within Ohio and Meigs County, including:

- The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients,

and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;

- The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Ohio and Federal law;
- The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the

use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Ohio and Federal law by not reporting these doctors instead; and,
- The Sales Representative Defendants falsely representing to prescribers and the public concerning the risk of addiction, abuse and diversion of OxyContin and its relative safety.
- The Sales Representative Defendants negligently and recklessly marketing, advertising, and promoting OxyContin in Meigs County and surrounding areas;
- The Sales Representative Defendants misrepresenting and misstating the addiction, abuse and/or diversion potential of OxyContin;
- The Sales Representative Defendants overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- The Sales Representative Defendants downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
- The Sales Representative Defendants overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
- The Sales Representative Defendants marketing OxyContin for indications and benefits that were not supported by substantial evidence; and
- The Sales Representative Defendants misrepresenting to health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

344. Defendants knew at the time that they made their misrepresentations and

omissions that 1.) they were false and 2.) had the tendency to influence the consumer choices of Plaintiff and its residents.

345. Defendants designed their misrepresentations and omissions for the purpose of influencing Plaintiff and its residents into relying upon them.

346. Defendants' acts and practices as alleged in this Complaint had a capacity or tendency to deceive. When considered from the perspective of a reasonable consumer, these acts or practices were likely to mislead Ohio consumers in Meigs County.

347. The Manufacturer Defendants' and Sales Representative Defendants' consistent, repeated, deceptive representations that their opioids had properties unsupported by medical literature did in fact deceive Plaintiff and its residents, causing them to both prescribe and consume opioids for the treatment of chronic pain conditions and suffer from addiction when they otherwise would not.

348. The Distributor and Physician Defendants' consistent, repeated, deceptive representations that they kept records as required by law and were prescribing opioids for legitimate medical purposes did in fact deceive Plaintiff and its residents, resulting in widespread addiction that otherwise would not have occurred.

349. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

350. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law

enforcement for the sake of its own profits.

351. Given the efforts taken by the Physician Defendants to obtain a medical license, operate a business, and present the outward appearance of legitimate medical practitioners, Plaintiff and its residents reasonably relied on the Physician Defendants representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

352. Plaintiff and its residents have been injured by reason of Defendants' violations of CSPA. Plaintiff's injuries were directly caused by Defendants' deceptive behavior, resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue. The health and wellbeing of the citizens of Meigs County, including those who have abused or will abuse prescription opioids, or were led to their addiction by the acts of Defendants, is a matter of vital and legitimate concern to Plaintiff and its citizens.

353. Defendants' conduct was willful or knowing under Ohio R.C. 1345.01 *et seq*.

354. Defendants' acts or practices alleged herein constitute unfair or deceptive acts or practices in violation of CSPA and have proximately caused and continue to cause an ascertainable loss of money and property to Plaintiff.

355. Every deceptive, unfair, and/or misrepresentative act by Defendants constitutes a separate and distinct violation of Ohio R.C. 1345.01 *et seq*., capable of repetition and affecting and impacting the public's interest. Defendants' acts in violation of CSPA are patently offensive to public policy, unethical, immoral, and oppressive.

356. Plaintiff is informed and believes that it is entitled to actual damages in an amount to be determined by the jury, and that Plaintiff is entitled to an award of treble damages under CSPA and an award of reasonable attorney's fees.

CLAIM TWO
FRAUD
(AGAINST ALL DEFENDANTS)

357. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

358. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- The Manufacturer Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- The Manufacturer Defendants' creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- The Manufacturer Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- The Manufacturer Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- The Manufacturer Defendants' sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling

regulations in violation of Ohio and Federal law;

- The Manufacturer Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Ohio and Federal law by not reporting these doctors instead; and,
- The Sales Representative Defendants falsely representing to prescribers and the public concerning the risk of addiction, abuse and diversion of OxyContin and its relative safety.
- The Sales Representative Defendants negligently and recklessly marketing, advertising, and promoting OxyContin in Meigs County and surrounding areas;

- The Sales Representative Defendants misrepresenting and misstating the addiction, abuse and/or diversion potential of OxyContin;
- The Sales Representative Defendants overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- The Sales Representative Defendants downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
- The Sales Representative Defendants overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
- The Sales Representative Defendants marketing OxyContin for indications and benefits that were not supported by substantial evidence; and
- The Sales Representative Defendants misrepresenting to health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

359. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

360. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

361. Given the incredible resources the Manufacturer Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon (and were right to rely upon) Defendants' misrepresentations and omissions, as stated above.

362. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied upon (and were right to rely

upon) the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

363. Given the efforts taken by the Sales Representative Defendants Plaintiff and its residents reasonably relied on the Sales Representatives, believing that they were accurately advertising concerning the risk of addiction, abuse and diversion of OxyContin and of its relative safety.

364. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff had no knowledge of the Defendants' falsehoods and Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

365. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

CLAIM THREE
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

366. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

367. The doctrine of unjust enrichment is meant to prevent the wrongful retention of a benefit in violation of good conscience and fundamental principles of justice and equity, or to prevent a double recovery. Unjust enrichment permits recovery of that amount the defendant has been unjustly enriched at the expense of the Plaintiff.

368. As an expected and intended result of their conscious wrongdoing as set

forth in this Complaint above, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.

369. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

370. Defendants wrongdoing directly caused Plaintiff to suffer increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue, without receiving any of the purported benefits deceptively promoted by Defendants.

371. Defendants acts and practices alleged herein were motivated by a desire to retain and increase market share and profits, and were undertaken in bad faith.

372. Meigs County has suffered injuries in paying for opioids, and the direct costs resulting from opioid use as a result of Defendants' unlawful conduct and are entitled to restitution or disgorgement.

373. Defendants have been unjustly enriched in the form of increased revenues and profits as a result of their deceptive marketing in violation of the laws of the state of Ohio. Under equitable principles and due to its unjust enrichment, Defendants should be required to disgorge any profits, plus interest, that were obtained as a result of its misrepresentations.

CLAIM FOUR
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

374. Plaintiff incorporate the allegations within all prior paragraphs of this Complaint as if they were fully set forth herein.

375. Distributor Defendants have a duty to exercise reasonable care in the distribution of opioids, as provided by state and federal law, to avoid, prevent, or attenuate third-party misconduct.

376. Distributor Defendants breached this duty by failing to take any action to prevent or reduce the distribution of opioids, as required by state and federal law, and instead participated in and enabled Defendants' misconduct.

377. Manufacturer Defendants and Sales Representative Defendants have a duty to exercise reasonable care in the manufacture, promotion, marketing, advertising, and distribution of opioids.

378. Manufacturer Defendants and Sales Representative Defendants breached this duty by promulgating deceptive, false, and misleading advertisements regarding their opioids, and the risk of addiction, abuse, and diversion and its relative safety, encouraging the medical community to prescribe opioids despite an unreasonable risk of addiction.

379. The Sales Representative Defendants have a duty to exercise reasonable care in the advertising of opioids. They breached this duty when they falsely advertised to prescribers of opioids and the public concerning the risk of addiction, abuse and diversion of OxyContin and of its relative safety to drug dealers and addicts for nonmedical purposes.

380. As a direct and a proximate result, Manufacturer Defendants, Distributor Defendants, and their agents, and Sales Representative Defendants have caused Plaintiff to suffer damages by (among other things) incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, Plaintiff has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, first responder services, and child

and family services for county residents and using county resources in relation to opioid use and abuse. Additionally, Plaintiff has suffered lost productivity from its workforce, thereby losing much needed tax revenue. The Defendants' acts are willful and wanton. In addition to actual damages, Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

CLAIM FIVE
NEGLIGENT MISREPRESENTATION
(AGAINST ALL DEFENDANTS)

381. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

382. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- The Manufacturer Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- The Manufacturer Defendants' creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- The Manufacturer Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- The Manufacturer Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- The Manufacturer Defendants' sponsoring, directly

distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Ohio and Federal law;
- The Manufacturer Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education

materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Ohio and Federal law by not reporting these doctors instead; and,

- The Sales Representative Defendants falsely representing to prescribers and the public concerning the risk of addiction, abuse and diversion of OxyContin and its relative safety.
- The Sales Representative Defendants negligently and recklessly marketing, advertising, and promoting OxyContin in Meigs County and surrounding areas;
- The Sales Representative Defendants misrepresenting and misstating the addiction, abuse and/or diversion potential of OxyContin;
- The Sales Representative Defendants overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- The Sales Representative Defendants downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
- The Sales Representative Defendants overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
- The Sales Representative Defendants marketing OxyContin for indications and benefits that were not supported by substantial evidence; and,
- The Sales Representative Defendants misrepresenting to health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

383. Defendants knew or should have known at the time that they made their misrepresentations and omissions that they were false.

384. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiffs.

385. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

386. Given the incredible resources the Manufacturer Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

387. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

388. Given the efforts taken by the Sales Representative Defendants to market, advertise and promote OxyContin, Plaintiff and its residents reasonably relied on the Sales Representative Defendants' representations that they accurately advertising to prescribers of opioids and the public concerning the risk of addiction, abuse and diversion of OxyContin.

389. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

390. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

CLAIM SIX
PUBLIC NUISANCE
OHIO PRODUCT LIABILITY ACT
OHIO REVISED CODE CHAPTER 2307.071 *ET SEQ.*
AND COMMON LAW
(AGAINST ALL DEFENDANTS)

391. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

392. Defendants, through the actions described in this Complaint, have created, or were a substantial factor in creating, a public nuisance by unreasonably interfering with a right common to the general public that worked to hurt, inconvenience, or damage and interfere with the enjoyment of life or property.

393. Plaintiff and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience. The interference of this right resulted from Defendants' illegal and deceptive marketing and distribution of opioids.

394. Defendants, individually and acting through their employees and agents, and in concert with each other, made unreasonable and/or unlawful use of their financial resources in an improper, indecent, and unwarranted fashion to wage a massive campaign of misrepresentations and omissions of facts, negligence, and violation of state laws material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- The Manufacturer Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- The Manufacturer Defendants' creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

- The Manufacturer Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- The Manufacturer Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- The Manufacturer Defendants' sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Ohio and Federal law;
- The Manufacturer Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' exclusively disseminating

misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

- The Manufacturer Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Ohio and Federal law by not reporting these doctors instead; and
- The Sales Representative Defendants falsely representing to prescribers and the public concerning the risk of addiction, abuse and diversion of OxyContin and of its relative safety.

395. The activities of Defendants that created a public nuisance worked as an obstruction or injury to Plaintiff and its residents, producing a material annoyance, inconvenience, discomfort, and/or hurt on Plaintiff and its residents by causing them to suffer actual damages directly caused by Defendants' deceptive, negligent, and/or unlawful behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

396. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

397. At all times relevant to the Complaint, Defendants exercised control over the instrumentalities constituting the nuisance, Defendants' actions were a substantial factor creating the public nuisance, and the public nuisance was foreseeable to Defendants. Without Defendants' actions, opioid use would not have become so

widespread in Meigs County, and the opioid epidemic that now exists would have been averted or would be much less severe.

CLAIM SEVEN
CONSTRUCTIVE FRAUD
(AGAINST ALL DEFENDANTS)

398. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

399. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- The Manufacturer Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- The Manufacturer Defendants' creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- The Manufacturer Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- The Manufacturer Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- The Manufacturer Defendants' sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front

Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Ohio and Federal law;

- The Manufacturer Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Ohio and Federal law by not reporting these doctors instead; and,
- Sales Representative Defendants falsely representing to prescribers and the public concerning the risk of addiction, abuse and diversion of OxyContin and of its

relative safety.

- The Sales Representative Defendants negligently and recklessly marketing, advertising, and promoting OxyContin in Meigs County and surrounding areas;
- The Sales Representative Defendants misrepresenting and misstating the addiction, abuse and/or diversion potential of OxyContin;
- The Sales Representative Defendants overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- The Sales Representative Defendants downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
- The Sales Representative Defendants overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
- The Sales Representative Defendants marketing OxyContin for indications and benefits that were not supported by substantial evidence; and,
- The Sales Representative Defendants misrepresenting to health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

400. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.

401. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiff.

402. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

403. Given the incredible resources the Manufacturer Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical

information, Plaintiff and its residents reasonably relied upon (and had the right to rely on) the Defendants' misrepresentations and omissions, as stated above.

404. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on (and had the right to rely on) the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

405. Given the efforts taken by the Sales Representative Defendants, Plaintiff and its residents reasonably relied on (and had the right to rely on) the Sales Representative Defendants' representations that they accurately advertising to prescribers of opioids and the public concerning the risk of addiction, abuse and diversion of OxyContin.

406. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff had no knowledge of the Defendants' falsehoods and Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

407. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

CLAIM EIGHT
NEGLIGENCE PER SE
(AGAINST ALL DEFENDANTS)

408. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

409. The Federal Food, Drug, and Cosmetic Act ("FDCA") places restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if the label is false or misleading "in any particular."[128] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[129] Furthermore, the FDCA specifies that drug advertisements must include a true statement of information and an advertisement fails to satisfy this requirement if it is:

> a) "false or misleading with respect to side effects, contraindications, or effectiveness"[130]; or,
> b) "Contains a representation or suggestion that a drugs is safer than it has been demonstrated to be by substantial evidence or substantial experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated."[131]

410. The Manufacturer Defendants breached their duties within Meigs County and Ohio, as specified by the FDCA when:

- marketing opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

[128] 21 U.S.C 352(a)
[129] 21 U.S.C.A. § 321(m)
[130] 21 CFR 202.1(e)(5)(i)
[131] 21 CFR 202.1(e)(6)(iv)

- creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Ohio and Federal law;
- endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and,
- making deceptive statements concerning the use of

opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

411. Section 4729-9 of the Ohio Administrative Code, entitled "Dangerous Drugs", requires distributors/wholesalers to create record keeping, including establishing and maintaining inventories and records of all transactions of dangerous drugs such as opioid pain medications. Similarily, Federal law at 21 CFR § 1301.74(b) imposes a non-delegable duty upon the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled substances. The [Distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [Distributor]. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[132] The stated purpose of the statutory scheme is to reduce the widespread diversion of controlled substances, like opioids, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[133]

412. The Distributor Defendants breached their duties within Meigs County and Ohio provided by state and federal law, and in many cases have admitted such breach, by:

- Failing to design and operate a system to disclose suspicious orders of opioids;
- Once compelled to design and operate a system to disclose suspicious orders of opioids, failing to report suspicious orders as required; and,
- Failing to avoid filling suspicious orders that were ultimately diverted.

413. Ohio State Law and Federal Law require medical practitioners distributing controlled substances to keep adequate records that are accurate and verify the

[132] 21 CFR § 1301.74(b)
[133] 1970 U.S.C.C.A.N. 4566, 4571-72

prescription history of patients receiving opioids. Furthermore, these laws make it illegal for medical practitioners to distribute opioids for nonmedical purposes outside a bona-fide practitioner-patient relationship.

414. The Distributor Defendants breached their duties to Meigs County and Ohio as specified above by:

- Distributing opioids for nonmedical purposes;
- Distributing opioids for nonmedical purposes outside a bona-fide practitioner-patient relationship;
- Failing to keep adequate records on patients being prescribed opioids;
- Failing to keep accurate records on patients being prescribed opioids; and,
- Failing to verify the prescription history of those whom they prescribed opioids.

415. All of the aforementioned statutory provisions are designed to protect both individuals and the community-at-large, like Nobel County and Ohio, from the addictive properties of opioids and the damages caused by opioid addiction, which includes the current opioid epidemic caused by Defendants that Plaintiff is forced to cope with and ameliorate by use of public funds.

416. As a direct and a proximate result of Defendants' acts and omissions that violated the listed statutory provisions, Defendants and their agents have caused Plaintiff to suffer damages by (among other things) incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, Plaintiff has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, first responder services, and child and family services for Residents and using Plaintiff's resources in relation to opioid use and abuse. Additionally, Plaintiff has suffered lost productivity from its workforce, thereby losing much needed tax revenue.

417. The Defendants' acts are willful and wanton. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

PRAYER FOR RELIEF

WHEREFORE Plaintiff demands judgment against Defendants, jointly and severally, awarding Plaintiff:

i. Compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

ii. Treble damages, penalties and costs, and reasonable attorney's fees pursuant to Ohio Revised Code Sections 1345.09(B);

iii. A reasonable amount of punitive damages to be determined by the jury at the trial of the matter;

iv. Interest, costs, and disbursements;

v. An injunction forcing Defendants to abate the opioid epidemic ravaging Ohio and Meigs County, enjoining the Defendants from marketing opioids as a.) safe for use in chronic pain patients; b.) carrying a low risk of addiction in long term use; and c.) needed in patients exhibiting signs of "pseudoaddiction."

vi. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

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JURY DEMAND

Plaintiffs demand a jury of 8 on all issues so triable.

Ethan Vessels (0076277)